REMARKS

The invention relates to the use of adipose tissue derived adult stem cells or stromal cells in combination with biocompatible, resorbable and non-resorbable materials for the repair of articular cartilage fractures.

Claims 1-19 are pending in the present application. Claims 1-5 and 9-12 are currently amended. The Examiner has objected to claims 2-5 and 9-10 for having improper dependency from claim 1. Specifically, the Examiner states that the dependency should be from a combination or a composition rather than from a cell. Therefore, Applicants have amended claim 1 to read "a composition comprising" and claims 2-5 and 9-10 to read "the composition of claim 1." Support for compositions comprising isolated adipose tissue-derived stem cells combined with a viscous biocompatible liquid material can be found, for example, on page 4, lines 7-12 of the specification as filed. Claims 2-5 have thereby been amended to correct their dependency from claim 1. Claims 11-12 have also been amended to correct a typographical error. Specifically, the word "insolated" has been corrected to read as "isolated." Support for this amendment can be found throughout the specification as filed, for example on page 2, lines 9-11. Therefore, no new matter has been added by way of these amendments.

Rejection of claim 10 under 35 U.S.C. §112, first paragraph

The Examiner has rejected claim 10 under 35 U.S.C. §112, first paragraph, for failing to comply with the written description requirement. Specifically, the Examiner alleges that Applicants generically claim a cell "modified with a nucleic acid", however, the specification does not contain an adequate description for the entire scope of this limitation and thus the claims. Applicants respectfully traverse this rejection for the following reasons.

In *Vas-Cath, Inc. v. Mahurkar*, 19 USPQ2d 1111 (Fed. Cir. 1991), the Court of Appeals for the Federal Circuit traced the development of the written description requirement under 35 U.S.C. §112, first paragraph. The *Vas-Cath* Court, in a unanimous opinion, noted approvingly that in a written description analysis, "[t]he primary concern is factual and depends on the nature of the invention and the amount of knowledge imparted to those skilled in the art by the disclosure." *Vas-Cath*, 19 USPQ2d at 1116 (quoting *In re Wertheim*, 191 USPQ 90, 96 (C.C.P.A. 1976)). After discussing the policy reasons underlying the requirement, the Court set forth the standard for the written description requirement:

> The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. . . . The test for sufficiency of support in a parent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter."

Vas-Cath, 19 USPQ2d at 1117 (emphasis added) (quoting *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 227 USPQ 177, 179 (Fed. Cir. 1985)). *Accord Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997). Therefore, it is well-settled that the knowledge of those skilled in the art informs the written description inquiry.

Applicants respectfully submit that claim 10, which recites the phrase "modified with a nucleic acid", is supported by the specification as filed and satisfies the written description requirement of 35 U.S.C. § 112, first paragraph, under current law. Applicants point out that there are two aspects of the phrase "modified with a nucleic acid", including (1) the modification process and (2) the nucleic acid that is to be modified. The modification process is described extensively in the specification beginning on page 16, line 4 and exemplary nucleic acids to be modified are described in Example 4. Applicants are not aware of a single case which holds that the each and every species, *e.g.*, every nucleic acid that could be modified, must be disclosed in order to satisfy the written description requirement. Indeed, in *In re Angstadt*, 190 USPQ 214, 218 (CCPA 1976), the court held that applicants "are not required to disclose every species encompassed by their claims even in an unpredictable art." Further, the only case cited by the Examiner (*Regents of the Univ. of California v. Eli Lilly & Co., supra*) does not support this conclusion for the reasons set forth below.

In *Regents of the Univ. of California v. Eli Lilly & Co., supra*, the Federal Circuit held that a description of the amino acid sequence of the A and B chains of human insulin did not provide a written description of human insulin cDNA where no part of the nucleic acid sequence of human insulin was disclosed. In contrast, in the present application the nucleic acids to be used in the invention (*e.g.*, bone morphogenetic protein receptors, bone morphogenetic receptors, vascular endothelial growth factor and/or platelet derived growth factor) and their sequences are well known, and numerous methods for modifying a cell with these nucleic acids have also been disclosed in the specification (see, *e.g.*, beginning page 16, line 4).

Further, the adequacy of the disclosure provided in the specification must be considered in light of the advanced state of knowledge in the relevant art in which there has been a comprehensive reduction to practice, *e.g.*, mammalian cells have been modified extensively by exogenous nucleic acids. In fact, the *Eli Lilly* Court, quoting *In re Angstadt*, 190 USPQ 214, 218 (CCPA 1976), recognized the long line of cases holding that applicants "are not required to disclose every species encompassed by their claims even in an unpredictable art." *Eli Lilly*, 43 USPQ2d at 1406. Thus, the holding of *Regents of the Univ. of California v. Eli Lilly & Co.*, is inappropriately relied upon under the present facts where extensive modification methodology and exemplary nucleic acids are cited in the specification, thereby providing ample written description of the subject matter of claim 10.

Whatever the holding of *Regents of the Univ. of California v. Eli Lilly & Co.*, the case is not applicable under the facts under consideration herein regarding the phrase "modified with a nucleic acid" of claim 10. As discussed in detail above, the specification as filed discloses numerous methods for introducing nucleic acids into a cell in order to modify the cell, and discloses multiple exemplary nucleic acids to be modified, all of which are well known in the art. Therefore, Applicants respectfully request reconsideration and withdrawal of this rejection by the Examiner.

Rejection of claims 1-19 for Double Patenting

The Examiner has rejected claims 1-19 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 19-30 of US Patent No. 6,429,013 ("the '013 patent" or "the grandparent patent"). The Examiner has also rejected claims 11-19 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of US Patent No. 6,841,150. Specifically, the Examiner asserts that although the conflicting claims are not identical, they are not patentably distinct.

Applicants understand that a timely filed Terminal Disclaimer in compliance with 37 CFR § 1.321(c) may be used to overcome such a non-statutory type of double patenting rejection. Accordingly, Applicants are filing the appropriate Terminal Disclaimer herewith. Therefore, Applicants respectfully submit that the Double Patenting rejection has been overcome.

Summary

Applicants respectfully submit that each rejection of the Examiner to the claims of the present application has been overcome and that claims 1-19 are now in condition for allowance. Reconsideration and allowance of these claims is respectfully requested at the earliest possible date.

Respectfully submitted,

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Enc: Terminal Disclaimer